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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

### IN RE: BRCA1- AND BRCA2-BASED HEREDITARY CANCER TEST PATENT LITIGATION

#### THIS DOCUMENT RELATES TO:

QUEST DIAGNOSTICS INCORPORATED, a Delaware corporation; and QUEST DIAGNOSTICS NICHOLS INSTITUTE, a California corporation,

Plaintiffs,

VS.

MYRIAD GENETICS, INC., A Delaware corporation,

# Defendants.

# ANSWER TO COMPLAINT FOR DECLARATORY JUDGMENT AND COUNTERCLAIMS

MDL Case No. 2:14-MD-02510-RJS

Case No. 2:14-CV-00152-RJS (*C.D. Cal. Case No. SACV13-01587 AG (DFMx*))

Judge Robert J. Shelby

Defendant and counterclaim plaintiff Myriad Genetics, Inc. ("Myriad"), by and through

its undersigned counsel, answers the Complaint for Declaratory Judgment ("Complaint") of plaintiffs and counterclaim defendants Quest Diagnostics Incorporated ("Quest Diagnostics") and Quest Diagnostics Nichols Institute ("Nichols Institute") (collectively, "Plaintiffs" or "Quest"), as follows:

#### **NATURE OF THIS ACTION**

1. Myriad denies that Quest is entitled to any form of relief under its Complaint, but admits that Quest is seeking a declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 5,747,282 (the "'282 patent"); 5,693,473 (the "'473 patent"); 5,709,999 (the "'999 patent"); 5,710,001 (the "'001 patent"); 5,753,441 (the "'441 patent"); 5,837,492 (the "'492 patent"); 6,033,857 (the "'857 patent"); 7,250,497 (the "'497 patent"); 6,083,698 (the "'698 patent"); 5,750,400 (the "'400 patent"); 5,654,155 (the "'155 patent"); 6,951,721 (the "'721 patent"); 6,492,109 (the "'109 patent"); and 6,051,379 (the "'379 patent") (collectively, the "patents-in-suit"). Myriad further denies that Quest does not infringe the patents-in-suit and denies that the patents-in-suit are invalid.

#### **PARTIES**

- 2. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in paragraph 2 of the Complaint and therefore denies the same.
- 3. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in paragraph 3 of the Complaint and therefore denies the same.
  - 4. Myriad admits the allegations of paragraph 4 of the Complaint.

### **JURISDICTION AND VENUE**

- 5. Myriad admits that Quest purports to file a civil action under United States patent law and the declaratory judgment statutes, but denies that Quest has properly done so or is entitled to relief under those statutes. Myriad denies that the United States District Court for the Central District of California had subject matter jurisdiction over this action at the time of filing of the Complaint.
- 6. Myriad admits that personal jurisdiction over Myriad is proper in either the United States District Court for the Central District of California or the United States District Court for the District of Utah as Myriad conducts business in both districts. Myriad otherwise denies the remaining allegations and characterizations of paragraph 6 of the Complaint.
- 7. Myriad admits that venue is proper in either the United States District Court for the Northern District of California or the United States District Court for the District of Utah. Myriad otherwise denies the remaining allegations and characterizations of paragraph 7 of the Complaint.

#### THE PATENTS IN SUIT

- 8. Myriad admits the allegations of paragraph 8 of the Complaint.
- 9. Myriad admits that it is the exclusive licensee of the '282 patent. Myriad denies that it has asserted that it has the sole right to enforce the '282 patent. Myriad denies the remaining characterizations of paragraph 9 of the Complaint.
  - 10. Myriad admits the allegations of paragraph 10 of the Complaint.

- 11. Myriad denies that it has purported to have sufficient rights by itself to enforce the '473 patent against Quest. Myriad denies the remaining characterizations of paragraph 11 of the Complaint.
  - 12. Myriad admits the allegations of paragraph 12 of the Complaint.
- 13. Myriad admits that it is the exclusive licensee of the '999 patent. Myriad denies that it has asserted that it has the sole right to enforce the '999 patent. Myriad denies the remaining characterizations of paragraph 13 of the Complaint.
  - 14. Myriad admits the allegations of paragraph 14 of the Complaint.
- 15. Myriad admits that it is the exclusive licensee of the '001 patent. Myriad denies that it has asserted that it has the sole right to enforce the '001 patent. Myriad denies the remaining characterizations of paragraph 15 of the Complaint.
  - 16. Myriad admits the allegations of paragraph 16 of the Complaint.
- 17. Myriad admits that it is the exclusive licensee of the '441 patent. Myriad denies that it has asserted that it has the sole right to enforce the '441 patent. Myriad denies the remaining characterizations of paragraph 17 of the Complaint.
  - 18. Myriad admits the allegations of paragraph 18 of the Complaint.
- 19. Myriad admits that it is the exclusive licensee of the '492 patent. Myriad denies that it has asserted that it has the sole right to enforce the '492 patent. Myriad denies the remaining characterizations of paragraph 19 of the Complaint.
  - 20. Myriad admits the allegations of paragraph 20 of the Complaint.

- 21. Myriad admits that it is the exclusive licensee of the '857 patent. Myriad denies that it has asserted that it has the sole right to enforce the '857 patent. Myriad denies the remaining characterizations of paragraph 21 of the Complaint.
  - 22. Myriad admits the allegations of paragraph 22 of the Complaint.
- 23. Myriad admits that it owns the '497 patent. Myriad denies the remaining characterizations of paragraph 23 of the Complaint.
  - 24. Myriad admits the allegations of paragraph 24 of the Complaint.
- 25. Myriad admits that it is the owner of the '698 patent, and that it has a right to enforce the '698 patent. Myriad denies the remaining characterizations of paragraph 25 of the Complaint.
  - 26. Myriad admits the allegations of paragraph 26 of the Complaint.
- 27. Myriad admits that it owns the '400 patent. Myriad denies the remaining characterizations of paragraph 27 of the Complaint.
  - 28. Myriad admits the allegations of paragraph 28 of the Complaint.
- 29. Myriad admits that it owns the '155 patent. Myriad denies the remaining characterizations of paragraph 29 of the Complaint.
  - 30. Myriad admits the allegations of paragraph 30 of the Complaint.
- 31. Myriad admits that it owns the '721 patent. Myriad denies the remaining characterizations of paragraph 31 of the Complaint.
  - 32. Myriad admits the allegations of paragraph 32 of the Complaint.

- 33. Myriad admits that it is the owner of the '109 patent, and that it has a right to enforce the '109 patent. Myriad denies the remaining characterizations of paragraph 33 of the Complaint.
  - 34. Myriad admits the allegations of paragraph 34 of the Complaint.
- 35. Myriad admits that it owns the '379 patent. Myriad denies the remaining characterizations of paragraph 35 of the Complaint.

#### **BACKGROUND**

- 36. The allegations of paragraph 36 of the Complaint are in the nature of a general technological background and require no response from Myriad. To the extent a response is required, Myriad is unaware of the specific source(s) for the information alleged in paragraph 36, is without knowledge or information sufficient to form a belief as to the truth of that information, and on that basis denies the same.
- 37. The allegations of paragraph 37 of the Complaint are in the nature of a general technological background and require no response from Myriad. To the extent a response is required, Myriad is unaware of the specific source(s) for the information alleged in paragraph 37, is without knowledge or information sufficient to form a belief as to the truth of that information, and on that basis denies the same.
  - 38. Myriad denies the allegations of paragraph 38 of the Complaint.
- 39. The allegations contained in paragraph 39 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.

- 40. The allegations contained in paragraph 40 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
  - 41. Myriad admits the allegations of paragraph 41 of the Complaint.
- 42. The allegations contained in paragraph 42 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
- 43. The allegations contained in paragraph 43 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
  - 44. Myriad admits the allegations of paragraph 44 of the Complaint.
- 45. The allegations contained in paragraph 45 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
- 46. The allegations contained in paragraph 46 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
- 47. The allegations contained in paragraph 47 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
  - 48. Myriad admits the allegations of paragraph 48 of the Complaint.
  - 49. Myriad admits the allegations of paragraph 49 of the Complaint.

- 50. Myriad admits that it brought suit against Ambry Genetics Corporation in the United States District Court for the District of Utah on July 9, 2013 and alleged infringement of at least certain claims of the '999, '282, '441, '721, '155, '400, '497, '492, '857, and '379 patents in the Complaint filed on that date. The other allegations of paragraph 50 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
  - 51. Myriad admits the allegations of paragraph 51 of the Complaint.
- 52. Myriad admits that it brought suit against Gene by Gene Limited in the United States District Court for the District of Utah on July 10, 2013 and alleged infringement of at least certain claims of the '999, '282, '441, '721, '155, '400, '497, '492, and '857 patents in the Complaint filed on that date. The other allegations of paragraph 52 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
- 53. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in paragraph 53 of the Complaint and therefore denies the same.
- 54. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in paragraph 54 of the Complaint and therefore denies the same.
- 55. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in paragraph 55 of the Complaint and therefore denies the same.

- 56. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in paragraph 56 of the Complaint and therefore denies the same. The allegations contained in paragraph 56 of the Complaint further represent an incomplete and otherwise inaccurate characterization of facts contained therein, and Myriad denies such allegations for this additional reason.
- 57. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 57 of the Complaint and therefore denies the same.
- 58. Myriad denies the allegations of paragraph 58 of the Complaint as of the date that Complaint was filed.
- 59. The allegations contained in paragraph 59 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
- 60. The allegations contained in paragraph 60 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.
- 61. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 61 of the Complaint and therefore denies the same. The allegations contained in the second sentence of paragraph 61 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same.

- 62. The allegations contained in paragraph 62 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same. To the extent paragraph 62 contains allegations about the state of mind of Dr. Conti, Myriad is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Myriad further notes that Mr. LaBrie is not an agent of Myriad, and alleges that Dr. Conti and Quest were aware that Mr. LaBrie was employed by Myriad RBM, not Myriad and was not Myriad's agent with regard to the patents-in-suit or any activities with regard to enforcement of rights under such patents.
- 63. The allegations contained in paragraph 63 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same. To the extent paragraph 63 contains allegations about the state of mind of Dr. Conti, Myriad is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Myriad further notes that Mr. LaBrie is not an agent of Myriad, and alleges that Dr. Conti and Quest were aware that Mr. LaBrie was employed by Myriad RBM, not Myriad and was not Myriad's agent with regard to the patents-in-suit or any activities with regard to enforcement of rights under such patents.
- 64. The allegations contained in paragraph 64 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same. To the extent paragraph 64 contains allegations about the state of mind of Dr. Conti or Quest, Myriad is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Myriad further notes that Mr. LaBrie is not an agent of Myriad, and alleges that Dr. Conti and Quest were aware that Mr.

LaBrie was employed by Myriad RBM, not Myriad and was not Myriad's agent with regard to the patents-in-suit or any activities with regard to enforcement of rights under such patents.

- 65. The allegations contained in paragraph 65 of the Complaint represent an incomplete and otherwise inaccurate characterization of facts contained therein. Myriad therefore denies the same. To the extent paragraph 65 contains allegations about the state of mind of Dr. Conti or Quest, Myriad is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Myriad further notes that Mr. LaBrie is not an agent of Myriad, and alleges that Dr. Conti and Quest were aware that Mr. LaBrie was employed by Myriad RBM, not Myriad and was not Myriad's agent with regard to the patents-in-suit or any activities with regard to enforcement of rights under such patents.
- 66. Myriad is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 66 of the Complaint and therefore denies the same. Myriad admits that Quest seeks a declaratory judgment of noninfringement and invalidity, but denies that Quest is entitled to such relief and further denies that at the time Quest filed its Complaint there was a definite, concrete, real and substantial controversy between Quest and Myriad of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Myriad otherwise denies the allegations and characterizations of paragraph 66.

# COUNT I (Declaratory Judgment of Noninfringement of the '282 patent)

67. Myriad incorporates its responses to paragraphs 1 through 66 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.

- 68. Myriad admits that Quest seeks a declaration of noninfringement of the '282 patent, but Myriad denies that Quest is entitled to such a declaration.
- 69. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT II** (Declaratory Judgment of Invalidity of the '282 patent)

- 70. Myriad incorporates its responses to paragraphs 1 through 69 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 71. Myriad denies the allegations of paragraph 71 of the Complaint.
- 72. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT III** (Declaratory Judgment of Noninfringement of the '473 patent)

- 73. Myriad incorporates its responses to paragraphs 1 through 72 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 74. Myriad admits that Quest seeks a declaration of noninfringement of the '473 patent, but Myriad denies that Quest is entitled to such a declaration.
- 75. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT IV**(Declaratory Judgment of Invalidity of the '473 patent)

- 76. Myriad incorporates its responses to paragraphs 1 through 75 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 77. Myriad denies the allegations of paragraph 77 of the Complaint.
- 78. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT V**(Declaratory Judgment of Noninfringement of the '999 patent)

- 79. Myriad incorporates its responses to paragraphs 1 through 78 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 80. Myriad admits that Quest seeks a declaration of noninfringement of the '999 patent, but Myriad denies that Quest is entitled to such a declaration.
- 81. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT VI** (Declaratory Judgment of Invalidity of the '999 patent)

- 82. Myriad incorporates its responses to paragraphs 1 through 81 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 83. Myriad denies the allegations of paragraph 83 of the Complaint.

84. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT VII**

# (Declaratory Judgment of Noninfringement of the '001 patent)

- 85. Myriad incorporates its responses to paragraphs 1 through 84 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 86. Myriad admits that Quest seeks a declaration of noninfringement of the '001 patent, but Myriad denies that Quest is entitled to such a declaration.
- 87. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT VIII**

# (Declaratory Judgment of Invalidity of the '001 patent)

- 88. Myriad incorporates its responses to paragraphs 1 through 87 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 89. Myriad denies the allegations of paragraph 89 of the Complaint.
- 90. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

### **COUNT IX**

#### (Declaratory Judgment of Noninfringement of the '441 patent)

91. Myriad incorporates its responses to paragraphs 1 through 90 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.

- 92. Myriad admits that Quest seeks a declaration of noninfringement of the '441 patent, but Myriad denies that Quest is entitled to such a declaration.
- 93. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT X**(Declaratory Judgment of Invalidity of the '441 patent)

- 94. Myriad incorporates its responses to paragraphs 1 through 93 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 95. Myriad denies the allegations of paragraph 95 of the Complaint.
- 96. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# <u>COUNT XI</u> (Declaratory Judgment of Noninfringement of the '492 patent)

- 97. Myriad incorporates its responses to paragraphs 1 through 96 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 98. Myriad admits that Quest seeks a declaration of noninfringement of the '492 patent, but Myriad denies that Quest is entitled to such a declaration.
- 99. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### COUNT XII

### (Declaratory Judgment of Invalidity of the '492 patent)

- 100. Myriad incorporates its responses to paragraphs 1 through 99 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 101. Myriad denies the allegations of paragraph 101 of the Complaint.
- 102. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

### **COUNT XIII**

### (Declaratory Judgment of Noninfringement of the '857 patent)

- 103. Myriad incorporates its responses to paragraphs 1 through 102 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 104. Myriad admits that Quest seeks a declaration of noninfringement of the '857 patent, but Myriad denies that Quest is entitled to such a declaration.
- 105. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT XIV**

# (Declaratory Judgment of Invalidity of the '857 patent)

- 106. Myriad incorporates its responses to paragraphs 1 through 105 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 107. Myriad denies the allegations of paragraph 107 of the Complaint.

108. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT XV**

### (Declaratory Judgment of Noninfringement of the '497 patent)

- 109. Myriad incorporates its responses to paragraphs 1 through 108 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 110. Myriad admits that Quest seeks a declaration of noninfringement of the '497 patent, but Myriad denies that Quest is entitled to such a declaration.
- 111. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT XVI**

## (Declaratory Judgment of Invalidity of the '497 patent)

- 112. Myriad incorporates its responses to paragraphs 1 through 111 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 113. Myriad denies the allegations of paragraph 113 of the Complaint.
- 114. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT XVII**

#### (Declaratory Judgment of Noninfringement of the '698 patent)

115. Myriad incorporates its responses to paragraphs 1 through 114 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.

- 116. Myriad admits that Quest seeks a declaration of noninfringement of the '698 patent, but Myriad denies that Quest is entitled to such a declaration.
- 117. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT XVIII**(Declaratory Judgment of Invalidity of the '698 patent)

- 118. Myriad incorporates its responses to paragraphs 1 through 117 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 119. Myriad denies the allegations of paragraph 119 of the Complaint.
- 120. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT XIX** (Declaratory Judgment of Noninfringement of the '400 patent)

- 121. Myriad incorporates its responses to paragraphs 1 through 120 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 122. Myriad admits that Quest seeks a declaration of noninfringement of the '400 patent, but Myriad denies that Quest is entitled to such a declaration.
- 123. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### COUNT XX

## (Declaratory Judgment of Invalidity of the '400 patent)

- 124. Myriad incorporates its responses to paragraphs 1 through 123 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 125. Myriad denies the allegations of paragraph 125 of the Complaint.
- 126. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT XXI**

### (Declaratory Judgment of Noninfringement of the '155 patent)

- 127. Myriad incorporates its responses to paragraphs 1 through 126 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 128. Myriad admits that Quest seeks a declaration of noninfringement of the '155 patent, but Myriad denies that Quest is entitled to such a declaration.
- 129. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### **COUNT XXII**

### (Declaratory Judgment of Invalidity of the '155 patent)

- 130. Myriad incorporates its responses to paragraphs 1 through 129 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 131. Myriad denies the allegations of paragraph 131 of the Complaint.

132. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# COUNT XXIII (Declaratory Judgment of Noninfringement of the '721 patent)

- 133. Myriad incorporates its responses to paragraphs 1 through 132 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 134. Myriad admits that Quest seeks a declaration of noninfringement of the '721 patent, but Myriad denies that Quest is entitled to such a declaration.
- 135. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT XXIV**(Declaratory Judgment of Invalidity of the '721 patent)

- 136. Myriad incorporates its responses to paragraphs 1 through 135 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 137. Myriad denies the allegations of paragraph 137 of the Complaint.
- 138. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT XXV**(Declaratory Judgment of Noninfringement of the '109 patent)

139. Myriad incorporates its responses to paragraphs 1 through 138 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.

- 140. Myriad admits that Quest seeks a declaration of noninfringement of the '109 patent, but Myriad denies that Quest is entitled to such a declaration.
- 141. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT XXVI**(Declaratory Judgment of Invalidity of the '109 patent)

- 142. Myriad incorporates its responses to paragraphs 1 through 141 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 143. Myriad denies the allegations of paragraph 143 of the Complaint.
- 144. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

# **COUNT XXVII**(Declaratory Judgment of Noninfringement of the '379 patent)

- 145. Myriad incorporates its responses to paragraphs 1 through 144 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
- 146. Myriad admits that Quest seeks a declaration of noninfringement of the '379 patent, but Myriad denies that Quest is entitled to such a declaration.
- 147. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### COUNT XXVIII

# (Declaratory Judgment of Invalidity of the '379 patent)

- 148. Myriad incorporates its responses to paragraphs 1 through 147 of this Answer to Complaint for Declaratory Judgment as if fully set forth herein.
  - 149. Myriad denies the allegations of paragraph 149 of the Complaint.
- 150. Myriad denies that an actual and justiciable controversy existed between the parties at the time the Complaint was filed, and further denies that Quest is entitled to any of the relief sought in the Complaint.

#### PRAYER FOR RELIEF

Myriad denies that any relief in favor of Quest is appropriate or warranted, and specifically denies that Quest is entitled to any of the relief set forth in paragraphs a. through d. of Quest's prayer for relief.

#### AFFIRMATIVE DEFENSES

To the extent not expressly admitted above, the factual allegations contained in the Complaint are denied. Without altering any applicable burdens of proof and in further response to the Complaint, Myriad alleges the following affirmative defenses:

### FIRST AFFIRMATIVE DEFENSE

Quest's Complaint fails to present a justiciable and concrete case or controversy of sufficient immediacy to invoke this Court's subject matter jurisdiction because, at the time Quest filed its Complaint, Myriad had not threatened or otherwise directed any action or statements to Quest sufficient to raise such a case or controversy. No such case or controversy existed prior to the time that Myriad, and others with interests in the patents-in-suit, brought suit against Quest in the United States District Court for the District of Utah.

### **SECOND AFFIRMATIVE DEFENSE**

Quest's Complaint herein is an improper anticipatory suit asserted for purposes of forum shopping and should be dismissed.

#### THIRD AFFIRMATIVE DEFENSE

The United States District Court for the Northern District of California is an inconvenient venue for this lawsuit, and this action, if not dismissed, should be transferred for all purposes to the United States District Court for the District of Utah.

### FOURTH AFFIRMATIVE DEFENSE

Upon agreement between the parties as reflected in the Joint Attorneys' Planning Meeting Report [Dkt. #40], Myriad expressly reserves all issues and defenses raised in its Motion to Dismiss or Transfer filed herein before the case was transferred by the Judicial Panel for Multidistrict Litigation for consolidated pretrial proceedings.

#### FIFTH AFFIRMATIVE DEFENSE

This lawsuit fails to include parties with an interest in the patents-in-suit.

#### SIXTH AFFIRMATIVE DEFENSE

The Complaint, and each and every claim for relief therein, fails to state facts sufficient to constitute a cause of action upon which relief can be granted.

#### SEVENTH AFFIRMATIVE DEFENSE

The Complaint, and each and every claim for relief therein, fails for lack of injury or damage suffered by Plaintiff.

### **EIGHTH AFFIRMATIVE DEFENSE**

Each claim of each of the patents-in-suit is valid, enforceable, and in full compliance with the patentability requirements of, *inter alia*, 35 U.S.C. §§ 101, 102, 103, and 112, and at least one claim of each of the patents-in-suit is infringed by Plaintiff.

#### **NINTH AFFIRMATIVE DEFENSE**

Myriad alleges that it is presently without knowledge or information sufficient to form a belief whether it may have additional, yet unasserted, affirmative defenses. Myriad therefore reserves the right to assert additional affirmative defenses if it acquires knowledge or information supporting such defenses.

#### COUNTERCLAIMS FOR PATENT INFRINGEMENT

1. Pursuant to Rule 13 of the Federal Rules of Civil Procedure, defendant and counterclaim plaintiff Myriad Genetics, Inc. ("Myriad" or "Counterclaim Plaintiff"), by and through its undersigned counsel, as a counterclaim against plaintiff and counterclaim defendants Quest Diagnostics Incorporated ("Quest Diagnostics") and Quest Diagnostics Nichols Institute ("Nichols Institute") (collectively, "Counterclaim Defendants" or "Quest") alleges as follows:

#### **JURISDICTION AND VENUE**

- 2. This counterclaim for patent infringement arises under the patent laws of the United States, specifically under Title 35 of the United States Code, Sections 271, *et seq*. Subject matter jurisdiction in this Court is founded upon 28 U.S.C. §§ 1331 and 1338(a).
  - 3. This Court<sup>1</sup> has personal jurisdiction over Counterclaim Defendants.

<sup>&</sup>lt;sup>1</sup> For purposes of these Counterclaims, "this Court," "this jurisdiction," "this judicial district," and "this district," mean the United States District Court for the Central District of California.

4. Venue is proper in the United States District Court for the Central District of California and in the United States District Court for the District of Utah pursuant to 28 U.S.C. §§ 1391(b) and/or 28 U.S.C. § 1400(b).

#### **PARTIES**

- 5. Myriad is a Delaware corporation, with its principal place of business at 320 Wakara Way, Salt Lake City, Utah 84108. Myriad owns United States Patent Nos. 5,654,155; 5,750,400; 6,051,379; 6,951,721; 7,250,497; 6,083,698; and 6,492,109. Further, Myriad is the exclusive licensee of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; 6,033,857; 5,693,473; and 5,710,001.
- 6. Myriad is informed and believes, and on that basis alleges, that counterclaim defendant Quest Diagnostics Incorporated is a Delaware corporation that has its principal place of business at 3 Giralda Farms, Madison, New Jersey 07940.
- 7. Myriad is informed and believes, and on that basis alleges, that counterclaim defendant Quest Diagnostics Nichols Institute is a California corporation that has its principal place of business at 33608 Ortega Highway, San Juan Capistrano, California 92690.

#### **GENERAL ALLEGATIONS**

8. Myriad is a molecular diagnostic company that develops and uses proprietary technologies that permit doctors and patients to understand the genetic basis of human disease and the role that genes play in the onset, progression, and treatment of disease. Myriad's technologies result in, and guide the development of, new molecular diagnostic products that assess an individual's risk for developing disease, identify a patient's likely response to drug therapy, and assess a patient's risk of disease progression and recurrence.

- 9. For healthcare providers, Myriad offers an array of genetic tests, prognostic tests and personalized medicine tests to help healthcare providers assess a patient's increased cancer risk, disease aggressiveness, and optimize efficacy of chemotherapy. Myriad's testing products provide healthcare providers with information to help make medical management decisions to reduce cancer risk and help make sure specific treatments are tailored for each individual patient.
- 10. For patients, Myriad offers tests that provide important clinical information to assist patients and their healthcare providers in assessing cancer risk so the patient can take preventative action to reduce the risk of disease and in making treatment decisions if the patient is diagnosed with cancer. Myriad improves patient care through the development of new products across multiple medical specialties.
- 11. In the early-to-mid 1990s, Myriad and its research partners discovered the genetic sequences of the BRCA1 and BRCA2 genes and mutations that increase a woman's risk of developing breast and ovarian cancer. Since that time, Myriad has invested over \$500 million to implement this discovery and create a molecular diagnostic test for hereditary breast and ovarian cancer related to the BRCA1 and BRCA2 genes. Myriad's efforts have revolutionized patient care and provided medical diagnosis and treatment options never thought possible.
- 12. Counterclaim Defendants offer laboratory services, including clinical diagnostic and genomic services, including testing and analysis of the BRCA1 and BRCA2 genes.
- 13. Counterclaim Defendants filed their Complaint herein on October 10, 2013, naming Myriad Genetics, Inc. (and no other parties), in the U.S. District Court for the

Central District of California, Case No. 8:13-cv-01587-AG-DFM, for a declaratory judgment that various patents are not infringed by Quest and are invalid. In the Complaint, Quest alleged that it "will soon commercially launch ... a novel two-part assay to detect hereditary alterations in two human genes, BRCA1 and BRCA2" that Counterclaim Defendants referred to as "Quest's BRCA Assay."

- 14. After filing the Complaint, and with knowledge of Myriad's patents, Counterclaim Defendants publicly announced on October 15, 2013, that they were offering for sale testing relating to the BRCA1 and BRCA2 genes. On information and belief, Counterclaim Defendants offer stand-alone tests comprising full gene sequencing and deletion/duplication analyses for the BRCA 1 and BRCA 2 genes.
- 15. After Counterclaim Defendants sued Myriad, and after Myriad reviewed the public information available regarding Counterclaim Defendants' products related to testing for the BRCA1 and BRCA2 genes, Myriad and others with ownership interests in such patents (hereinafter collectively "Plaintiffs") sued Quest in this United States District Court for the District of Utah on October 22, 2013, for infringement United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; 6,033,857; 6,051,379; 6,951,721; and 7,250,497. Plaintiffs' October 22, 2013 Complaint did not assert infringement of United States Patent Nos. 5,654,155; 5,750,400; 6,083,698; 5,693,473; 5,710,001; or 6,492,109 because Plaintiffs had insufficient information regarding Quest's products to ascertain whether any claims of those patents were necessarily implicated by Quest's products. *See* Complaint [Dkt.#2] at ¶ 19.
- 16. Simultaneously with filing suit against Quest, Plaintiffs sent Quest a letter informing Quest of Plaintiffs' Complaint, the patents included in it, and requesting that Quest

"provide information and documentation ... regarding the processes, procedures, protocols, and instrumentation used by" Quest in its products, "including, without limitation, Quest's BRCAvantageTM Comprehensive, BRCAvantageTM Ashkenazi Jewish Screen, BRCAvantageTM Single Site, BRCAvantageTM Rearrangements products, and any other tests that include testing or analysis of the BRCA1 or BRCA2 genes, from which [Plaintiffs] may determine whether [the other six patents included in this Declaratory Judgment Suit, but not included in Plaintiffs' Original Complaint] are in fact implicated and evaluate whether the Complaint in the Utah litigation should be amended." Quest responded by letter on October 30, 2013, declining to provide any information regarding its products other than through formal discovery processes.

17. Accordingly, Plaintiffs amended their Complaint to provisionally allege, on information and belief, that Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe United States Patent Nos. 5,654,155; 5,750,400; 6,083,698; 5,693,473; 5,710,001; and 6,492,109 by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, selling, and/or causing to be offered or sold products that infringe at least one claim of each of those patents literally and/or under the doctrine of equivalents. As a result of Quest's refusal to provide information regarding its products, Quest's declaratory judgment suit against Myriad asserting non-infringement of those patents, and because Myriad is presently not aware of any technique that can be used to definitively establish that Quest's products practice the inventions claimed in those patents, Myriad resorts to the judicial process and aid of discovery to obtain under appropriate judicial

safeguards such information as is required to confirm its belief and to present to the Court evidence that Counterclaim Defendants infringe one or more claims of each of those patents.

#### FIRST COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 5,709,999)

- 18. Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 17, inclusive.
- 19. United States Patent No. 5,709,999 (the "'999 Patent"), was duly and legally issued by the United States Patent and Trademark Office on January 20, 1998. The University of Utah Research Foundation ("University of Utah") is the owner and Myriad is the exclusive licensee of the '999 Patent. A true and correct copy of the '999 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 20. Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '999 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, and selling and/or causing to be offered or sold their BRCAvantage<sup>TM</sup> Comprehensive, BRCAvantage<sup>TM</sup> Ashkenazi Jewish Screen, BRCAvantage<sup>TM</sup> Single Site, and BRCAvantage<sup>TM</sup> Rearrangements products that infringe at least the following claim of the '999 patent literally and/or under the doctrine of equivalents: Claims 5, 6, 7, 10, 24, 25, 33, and/or 34.
- 21. Myriad and others have been damaged and have suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.

- 22. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein. Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 23. Counterclaim Defendants have willfully infringed the '999 Patent.
- 24. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

#### SECOND COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 5,747,282)

- 25. Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 24, inclusive.
- 26. United States Patent No. 5,747,282 (the "'282 Patent") was duly and legally issued by the United States Patent and Trademark Office on May 5, 1998. The University of Utah, along with the Public Health Service, through the National Institutes of Health ("PHS"), are the owners, and Myriad is the exclusive licensee, of the '282 Patent. A true and correct copy of the '282 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 27. Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '282 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, and selling and/or causing to be offered or sold their BRCAvantage<sup>TM</sup> Comprehensive, BRCAvantage<sup>TM</sup> Ashkenazi Jewish Screen, and

BRCAvantage<sup>TM</sup> Single Site products that infringe at least the following claims of the '282 patent literally and/or under the doctrine of equivalents: Claims 6, 16, and/or 17.

- 28. Myriad and others have been damaged and have suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 29. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein. Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 30. Counterclaim Defendants have willfully infringed the '282 Patent.
- 31. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

#### THIRD COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 5,753,441)

- 32. Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 31, inclusive.
- 33. United States Patent No. 5,753,441 (the "'441 Patent") was duly and legally issued by the United States Patent and Trademark Office on May 19, 1998. The University of Utah and PHS are the owners, and Myriad is the exclusive licensee, of the '441 Patent. A true and correct copy of the '441 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.

- of, and/or inducing others to infringe the '441 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, and selling and/or causing to be offered or sold their BRCAvantage<sup>TM</sup> Comprehensive, BRCAvantage<sup>TM</sup> Ashkenazi Jewish Screen, BRCAvantage<sup>TM</sup> Single Site, and BRCAvantage<sup>TM</sup> Rearrangements products that infringe at least the following claims of the '441 patent literally and/or under the doctrine of equivalents: Claims 7, 8, 9, 12, 22, 23, 24, and/or 26.
- 35. Myriad and others have been damaged and have suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 36. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein. Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 37. Counterclaim Defendants have willfully infringed the '441 Patent.
- 38. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

#### **FOURTH COUNTERCLAIM FOR RELIEF**

(Infringement of United States Patent No. 5,837,492)

39. Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 38, inclusive.

- 40. United States Patent No. 5,837,492 (the "'492 Patent") was duly and legally issued by the United States Patent and Trademark Office on November 17, 1998. The University of Utah, The Trustees of the University of Pennsylvania ("University of Pennsylvania"), the HSC Research and Development Limited Partnership ("Hospital for Sick Children"), and Endorecherche, Inc. ("Endorecherche") are the owners, and Myriad is the exclusive licensee, of the '492 Patent. A true and correct copy of the '492 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 41. Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '492 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, and selling and/or causing to be offered or sold their BRCAvantage<sup>TM</sup> Comprehensive, BRCAvantage<sup>TM</sup> Ashkenazi Jewish Screen, and BRCAvantage<sup>TM</sup> Single Site products that infringe at least the following claims of the '492 patent literally and/or under the doctrine of equivalents: Claims 29 and/or 30.
- 42. Myriad and others have been damaged and have suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 43. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein. Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 44. Counterclaim Defendants have willfully infringed the '492 Patent.

45. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

#### FIFTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 6,033,857)

- 46. Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 45, inclusive.
- 47. United States Patent No. 6,033,857 (the "'857 Patent'') was duly and legally issued by the United States Patent and Trademark Office on March 7, 2000. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche are the owners, and Myriad is the exclusive licensee, of the '857 Patent. A true and correct copy of the '857 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 48. Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '857 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, and selling and/or causing to be offered or sold their BRCAvantage<sup>TM</sup> Comprehensive, BRCAvantage<sup>TM</sup> Ashkenazi Jewish Screen, BRCAvantage<sup>TM</sup> Single Site, and BRCAvantage<sup>TM</sup> Rearrangements products that infringe at least the following claim of the '857 patent literally and/or under the doctrine of equivalents: Claim 4.
- 49. Myriad and others with interests in the '857 patent have been damaged and have suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.

- 50. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein. Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 51. Counterclaim Defendants have willfully infringed the '857 Patent.
- 52. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

## SIXTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 6,051,379)

- 53. Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 52, inclusive.
- 54. United States Patent No. 6,051,379 (the "'379 Patent") was duly and legally issued by the United States Patent and Trademark Office on April 18, 2000. Myriad is the owner of the '379 Patent. A true and correct copy of the '379 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 55. Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '379 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, and selling and/or causing to be offered or sold their BRCAvantage<sup>TM</sup> Comprehensive, BRCAvantage<sup>TM</sup> Single Site, and BRCAvantage<sup>TM</sup> Rearrangements products that infringe at least the following claims of the '379 patent literally

and/or under the doctrine of equivalents: Claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 32, 33, 40, and/or 42.

- 56. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 57. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein, and Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 58. Counterclaim Defendants have willfully infringed the '379 Patent.
- 59. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

#### SEVENTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 6,951,721)

- 60. Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 59, inclusive.
- 61. United States Patent No. 6,951,721 (the "'721 Patent'') was duly and legally issued by the United States Patent and Trademark Office on October 5, 2005. Myriad is the owner of the '721 Patent. A true and correct copy of the '721 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.

- 62. Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '721 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, and selling and/or causing to be offered or sold their BRCAvantage™ Comprehensive, BRCAvantage™ Ashkenazi Jewish Screen, and BRCAvantage™ Single Site products that infringe at least the following claim of the '721 patent literally and/or under the doctrine of equivalents: Claim 5.
- 63. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 64. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein, and Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 65. Counterclaim Defendants have willfully infringed the '721 Patent.
- 66. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

#### EIGHTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 7,250,497)

67. Counterclaim Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 66, inclusive.

- 68. United States Patent No. 7,250,497 (the "'497 Patent'') was duly and legally issued by the United States Patent and Trademark Office on July 31, 2007. Myriad is the owner of the '497 Patent. A true and correct copy of the '497 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 69. Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '497 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold their BRCAvantage™ Comprehensive, BRCAvantage™ Single Site, and BRCAvantage™ Rearrangements products that infringe at least the following claims of the '497 patent literally and/or under the doctrine of equivalents: Claims 3, 4, 5, 6, 7, 8, 11, 14, 17, and/or 19.
- 70. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 71. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein, and Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
  - 72. Counterclaim Defendants have willfully infringed the '497 Patent.
- 73. Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

### NINTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 5,654,155)

- 74. Counterclaim Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 73, inclusive.
- 75. United States Patent No. 5,654,155 (the "'155 Patent'') was duly and legally issued by the United States Patent and Trademark Office on August 5, 1997. Myriad is the owner of the '155 Patent. A true and correct copy of the '155 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 76. On information and belief, Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '155 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, selling, and/or causing to be offered or sold products that infringe at least one claim of the '155 patent literally and/or under the doctrine of equivalents. In the absence of information from Counterclaim Defendants concerning their products, Myriad is presently not aware of any technique that can be used to definitively establish that Counterclaim Defendants' products practice the inventions claimed in the '155 patent. For that reason, Myriad has sought from Counterclaim Defendants information that would assist Myriad in confirming whether Counterclaim Defendants' products fall within the lawful scope of one or more claims of the '155 patent. Counterclaim Defendants have refused to provide this information other than through formal judicial discovery processes. Counterclaim Defendants also seek a declaratory judgment from this Court that various patents, including the '155 patent, are not infringed by Counterclaim Defendants' products and are invalid. Accordingly, in the absence of such information and as permitted by Hoffman-LaRoche Inc. v. Invamed, Inc., 213 F.3d 1359 (Fed. Cir. 2000), Myriad resorts to the judicial process and

aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief and to present to the Court evidence that Counterclaim Defendants infringe one or more claims of the '155 patent.

- 77. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 78. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein, and Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendant's acts.
- 79. On information and belief, Counterclaim Defendants have willfully infringed the '155 Patent.
- 80. On information and belief, Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

#### TENTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 5,750,400)

- 81. Counterclaim Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 80, inclusive.
- 82. United States Patent No. 5,750,400 (the "'400 Patent") was duly and legally issued by the United States Patent and Trademark Office on May 12, 1998. Myriad is the

owner of the '400 Patent. A true and correct copy of the '400 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.

83. On information and belief, Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '400 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, selling, and/or causing to be offered or sold products that infringe at least one claim of the '400 patent literally and/or under the doctrine of equivalents. In the absence of information from Counterclaim Defendants concerning their products, Myriad is presently not aware of any technique that can be used to definitively establish that Counterclaim Defendants' products practice the inventions claimed in the '400 patent. For that reason, Myriad has sought from Counterclaim Defendants information that would assist Myriad in confirming whether Counterclaim Defendants' products fall within the lawful scope of one or more claims of the '400 patent. Counterclaim Defendants have refused to provide this information other than through formal judicial discovery processes. Counterclaim Defendants also seek a declaratory judgment from this Court that various patents, including the '400 patent, are not infringed by Counterclaim Defendants' products and are invalid. Accordingly, in the absence of such information and as permitted by Hoffman-LaRoche Inc. v. Invamed, Inc., 213 F.3d 1359 (Fed. Cir. 2000), Myriad resorts to the judicial process and aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief and to present to the Court evidence that Counterclaim Defendants infringe one or more claims of the '400 patent.

- 84. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 85. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein, and Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendant's acts.
- 86. On information and belief, Counterclaim Defendants have willfully infringed the '400 Patent.
- 87. On information and belief, Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

## **ELEVENTH COUNTERCLAIM FOR RELIEF**

(Infringement of United States Patent No. 6,083,698)

- 88. Counterclaim Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 87, inclusive.
- 89. United States Patent No. 6,083,698 (the "'698 Patent") was duly and legally issued by the United States Patent and Trademark Office on July 4, 2000. Myriad is the owner of the '698 Patent. A true and correct copy of the '698 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 90. On information and belief, Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '698 patent by making,

manufacturing, promoting, marketing, advertising, distributing, offering for sale, selling, and/or causing to be offered or sold products that infringe at least one claim of the '698 patent literally and/or under the doctrine of equivalents. In the absence of information from Counterclaim Defendants concerning their tests, Myriad is presently not aware of any technique that can be used to definitively establish that Counterclaim Defendants' products practice the inventions claimed in the '698 patent. For that reason, Myriad has sought from Counterclaim Defendants information that would assist Myriad in confirming whether Counterclaim Defendants' products fall within the lawful scope of one or more claims of the '698 patent. Counterclaim Defendants have refused to provide this information other than through formal judicial discovery processes. Counterclaim Defendants also seek a declaratory judgment from this Court that various patents, including the '698 patent, are not infringed by Counterclaim Defendants' products and are invalid. Accordingly, in the absence of such information and as permitted by Hoffman-LaRoche Inc. v. Invamed, Inc., 213 F.3d 1359 (Fed. Cir. 2000), Myriad resorts to the judicial process and aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Counterclaim Defendants infringe one or more claims of the '698 patent.

- 91. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 92. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent

infringement as alleged herein, and Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendant's acts.

- 93. On information and belief, Counterclaim Defendants have willfully infringed the '698 Patent.
- 94. On information and belief, Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

### TWELFTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 5,693,473)

- 95. Counterclaim Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 94, inclusive.
- 96. United States Patent No. 5,693,473 (the "'473 Patent") was duly and legally issued by the United States Patent and Trademark Office on December 2, 1997. The University of Utah is the owner, and Myriad is the exclusive licensee, of the '473 Patent. A true and correct copy of the '473 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 97. On information and belief, Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '473 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, selling, and/or causing to be offered or sold products that infringe at least one claim of the '473 patent literally and/or under the doctrine of equivalents. In the absence of information from Counterclaim Defendants concerning their tests, Myriad is presently not aware of any technique that can be used to definitively establish that Counterclaim Defendants' products practice the inventions

claimed in the '473 patent. For that reason, Myriad has sought from Counterclaim Defendants information that would assist Myriad in confirming whether Counterclaim Defendants' products fall within the lawful scope of one or more claims of the '473 patent. Counterclaim Defendants have refused to provide this information other than through formal judicial discovery processes. Counterclaim Defendants also seek a declaratory judgment from this Court that various patents, including the '473 patent, are not infringed by Counterclaim Defendants' products and are invalid. Accordingly, in the absence of such information provided by Counterclaim Defendants and as permitted by *Hoffman-LaRoche Inc. v. Invamed, Inc.*, 213 F.3d 1359 (Fed. Cir. 2000), Myriad resorts to the judicial process and aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Counterclaim Defendants infringe one or more claims of the '473 patent.

- 98. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 99. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein. Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
- 100. On information and belief, Counterclaim Defendants have willfully infringed the '473 Patent.

101. On information and belief, Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

# THIRTEENTH COUNTERCLAIM FOR RELIEF

(Infringement of United States Patent No. 5,710,001)

- 102. Counterclaim Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 101, inclusive.
- 103. United States Patent No. 5,710,001 (the "'001 Patent") was duly and legally issued by the United States Patent and Trademark Office on January 20, 1998. The University of Utah and PHS are the owners, and Myriad is the exclusive licensee, of the '001 Patent. A true and correct copy of the '001 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 104. On information and belief, Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '001 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, selling, and/or causing to be offered or sold products that infringe at least one claim of the '001 patent literally and/or under the doctrine of equivalents. In the absence of information from Counterclaim Defendants concerning their products, Myriad is presently not aware of any technique that can be used to definitively establish that Counterclaim Defendants' products practice the inventions claimed in the '001 patent. For that reason, Myriad has sought from Counterclaim Defendants information that would assist Myriad in confirming whether Counterclaim Defendants' products fall within the lawful scope of one or more claims of the '001 patent. Counterclaim Defendants have refused to provide this information other than through formal judicial discovery processes.

Counterclaim Defendants also seek a declaratory judgment from this Court that various patents, including the '001 patent, are not infringed by Counterclaim Defendants' products and are invalid. Accordingly, in the absence of such information provided by Counterclaim Defendants and as permitted by *Hoffman-LaRoche Inc. v. Invamed, Inc.*, 213 F.3d 1359 (Fed. Cir. 2000), Myriad resorts to the judicial process and aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Counterclaim Defendants infringe one or more claims of the '001 patent.

- 105. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 106. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein. Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
- 107. On information and belief, Counterclaim Defendants have willfully infringed the '001 Patent.
- 108. On information and belief, Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

## **FOURTEENTH COUNTERCLAIM FOR RELIEF**

(Infringement of United States Patent No. 6,492,109)

- 109. Counterclaim Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 108, inclusive.
- 110. United States Patent No. 6,492,109 (the "'109 Patent') was duly and legally issued by the United States Patent and Trademark Office on December 10, 2002. Myriad is the owner of the '109 Patent. A true and correct copy of the '109 Patent is attached to Quest's Complaint for Declaratory Judgment and incorporated herein by reference.
- 111. On information and belief, Counterclaim Defendants are infringing, contributing to the infringement of, and/or inducing others to infringe the '109 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale, selling, and/or causing to be offered or sold products that infringe at least one claim of the '109 patent literally and/or under the doctrine of equivalents. In the absence of information from Counterclaim Defendants concerning their products, Myriad is presently not aware of any technique that can be used to definitively establish that Counterclaim Defendants' products practice the inventions claimed in the '109 patent. For that reason, Myriad has sought from Counterclaim Defendants information that would assist Myriad in confirming whether Counterclaim Defendants' products fall within the lawful scope of one or more claims of the '109 patent. Counterclaim Defendants have refused to provide this information other than through formal judicial discovery processes. Counterclaim Defendants also seek a declaratory judgment from this Court that various patents, including the '109 patent, are not infringed by Counterclaim Defendants' products and are invalid. Accordingly, in the absence of such information provided by Counterclaim Defendants

and as permitted by *Hoffman-LaRoche Inc. v. Invamed, Inc.*, 213 F.3d 1359 (Fed. Cir. 2000), Myriad resorts to the judicial process and aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Counterclaim Defendants infringe one or more claims of the '109 patent.

- 112. Myriad has been damaged and has suffered irreparable injury due to Counterclaim Defendants' acts of infringement, and Myriad will continue to suffer irreparable injury unless Counterclaim Defendants' acts are enjoined.
- 113. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Counterclaim Defendants' acts of patent infringement as alleged herein, and Myriad is entitled to recover from Counterclaim Defendants the damages sustained as a result of Counterclaim Defendants' acts.
- 114. On information and belief, Counterclaim Defendants have willfully infringed the '109 Patent.
- 115. On information and belief, Counterclaim Defendants' acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

### **DEMAND FOR JURY TRIAL**

116. Myriad demands a trial by jury on all matters herein so triable.

### RELIEF REQUESTED

WHEREFORE, Counterclaim Plaintiff Myriad prays for Judgment as follows:

a. That Counterclaim Defendants have infringed, contributed to the infringement of, and induced infringement of, literally and/or under the doctrine of equivalents,

the asserted claims of the '999, '282, '441, '492, '857, '379, '721, '497, '155, '400, '698, '473, '001, and '109 patents;

- b. That Counterclaim Defendants and their subsidiaries, affiliates, parents, successors, assigns, officers, agents, servants, employees, attorneys, and all other persons acting in concert or in participation with them, be temporarily and preliminarily enjoined during the pendency of this action, and permanently enjoined thereafter, from infringing the '999, '282, '441, '492, '857, '379, '721, '497, '155, '400, '698, '473, '001, and '109 patents, and specifically from directly or indirectly making, using, selling, offering for sale, or importing any products or services embodying the inventions of the '999, '282, '441, '492, '857, '379, '721, '497, '155, '400, '698, '473, '001, and '109 patents, including, without limitation, Counterclaim Defendants' BRCAvantage<sup>TM</sup> Comprehensive; BRCAvantage<sup>TM</sup> Ashkenazi Jewish Screen; BRCAvantage<sup>TM</sup> Single Site; BRCAvantage<sup>TM</sup> Rearrangements products, during the life of the claims of the '999, '282, '441, '492, '857, '379, '721, '497, '155, '400, '698, '473, '001, and '109 patents without Myriad's express written authority;
- c. That Myriad be awarded all damages attributable to Counterclaim Defendants' infringement of the '999, '282, '441, '492, '857, '379, '721, '497, '155, '400, '698, '473, '001, and '109 patents in an amount according to proof at trial, but not less than a reasonable royalty;
- d. That Counterclaim Defendants be ordered to deliver to Myriad, for destruction at Myriad's option, all products that infringe the '999, '282, '441, '492, '857, '379, '721, '497, '155, '400, '698, '473, '001, and '109 patents;

- e. That Counterclaim Defendants be required to account for all gains, profits, advantages, and unjust enrichment derived from their violations of the law;
  - f. That Quest's infringement be deemed willful;
- g. That this case be deemed "exceptional" within the meaning of 35 U.S.C. § 285;
- h. That Myriad be awarded its reasonable attorneys' fees incurred in connection with this matter;
- i. That Myriad be awarded enhanced damages and/or costs pursuant to 35
   U.S.C. § 285 and/or applicable law;
- j. That Myriad be awarded its costs of suit, and an assessment of interest; and,
- k. That the Court award Myriad such other, further, and different relief as the evidence may require and as the Court deems proper under the circumstances.

Dated: May 6<sup>th</sup>, 2014.

### /s/ Michael R. McCarthy

DAVID G. MANGUM
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# **CERTIFICATE OF SERVICE**

On this 6<sup>th</sup> day of May 2014, I certify that I electronically filed the foregoing

ANSWER TO COMPLAINT FOR DECLARATORY JUDGMENT AND

COUNTERCLAIMS with the Clerk of Court using the CM/ECF system that will send an electronic notification to counsel of record for all of the parties.

/s/ Michael R. McCarthy